

IMPORT HEALTH STANDARD FOR THE IMPORTATION OF FROZEN PORCINE SEMEN INTO NEW ZEALAND FROM THE UNITED STATES OF AMERICA

1. IMPORT HEALTH STANDARD

Pursuant to section 22 of the Biosecurity Act 1993, this document is the import health standard for the importation of frozen porcine semen into new Zealand from the United States of America.

2. IMPORT HEALTH PERMIT

2.1 Prior to importation, it is mandatory that the importer applies for an import health permit, which authorises the importation of animal semen into New Zealand. This permit is obtained from:

The Chief Veterinary Officer
Ministry of Agriculture
P O Box 2526, Wellington, New Zealand.

2.2 An import health permit will be issued for a single consignment only.

2.3 Attached to, and an integral part of the import health permit, is the current import health standard which describes the conditions under which the animal semen may be imported to New Zealand.

3. INFORMATION TO BE SUPPLIED BY THE IMPORTER

The importer shall supply the following information:

- 3.1 name and address of exporter;
- 3.2 name and address of the semen collection center;
- 3.3 breed and identification of donor boars;
- 3.4 number of straws to be imported.

4. REVIEW OF IMPORT HEALTH STANDARD

The import health standard may be reviewed and amended if there are changes in New Zealand's import policy, or the animal health status of the exporting country, or for any other reason, at the discretion of the Chief Veterinary Officer.

5. DOCUMENTATION ACCOMPANYING THE CONSIGNMENT

The import health permit and all the required certification (which must be in English or a bilingual ((language of specified country)/English form) must accompany the consignment to

New Zealand. The required documentation is:

- 5.1 Zoosanitary certificate;
- 5.2 Veterinary Certificate A, completed and signed by the veterinary surgeon appointed to the semen collection center.
- 5.3 Veterinary Certificate B, completed and signed by a government veterinary officer of the country of export.
- 5.4 copies of laboratory reports for all serological testing conducted according to the requirements of Veterinary Certificate A.

6. IMPORTER'S RESPONSIBILITIES

- 6.1 All costs involved with the selection, testing, treatment, transport, quarantine servicing must be borne by the importer or agent as appropriate.
- 6.2 The importer or agent must make all arrangements for transport and obtain necessary transit authorities from any countries on the transport route.
- 6.3 Details of transport and arrival times must be supplied to the MAF Veterinary Officer at the port or airport of entry not less than 7 days in advance of importation.

7. EQUIVALENCE

The health conditions stated within this import health standard have been agreed as being suitable for trade between the exporting and the importing countries. It is expected that the semen will meet the conditions in every respect.

Occasionally it is found that, due to circumstances beyond the control of the importer or exporter, the semen does not comply completely with the requirements. In such cases, applications for equivalence will be considered prior to importation and issued at the discretion of the New Zealand Ministry of Agriculture, but only if the following information is provided by the certifying government's Veterinary Authorities:

- 7.1 which clause/s of the health requirements cannot be met and how this has occurred;
- 7.2 the reason the semen is considered to be of an equivalent health status and/or what proposal is made to return the semen to an equivalent health status as set out in the health conditions;
- 7.3 the reasons why the Veterinary Authorities believe this proposal should be acceptable to the New Zealand Ministry of Agriculture and their recommendation for its acceptance.

8. ELIGIBILITY

- 8.1 Donor boars must have been born in, and resident since birth in, the USA.
- 8.2 Donor boars must originate from herds with documented absence of prior clinical signs

of Porcine Reproductive and Respiratory Syndrome (PRRS).

8.3 The donor boars must originate from herds which have never used a modified live PRRS virus vaccine nor introduced pigs from herds that have used a modified live PRRS virus vaccine.

8.4 Donor boars must originate from herds from which, within two months prior to the date of entry of the donor boars into the isolation facility, a randomly selected number of grower pigs at least equal to that calculated below (Cannon and Roe, 1982) has been tested using an approved multi-valent ELISA test for PRRS with a negative result in each case:

$$\begin{array}{llll} \text{Number of growers tested} & = & (1-(1-\alpha)^{1/n})(N-n/2)+1 \\ \text{Where, } N & = & \text{the number of grower pigs in the herd} \\ \alpha & = & \text{the level of confidence} \\ & = & 0.99 \\ n & = & \text{the minimum expected number of seropositive pigs} \\ & = & 0.10 \times (N) \end{array}$$

8.5 The semen must be in straws. Semen in pellets or ampoules is not acceptable.

9. ISOLATION

9.1 Prior to entry into the semen collection center, the donor boars must have completed a 5 week period of isolation in a facility which meets the location and facilities requirements of Sections 1 and 2 of Appendix 1 *MAF standards for semen collection centers for the collection of porcine semen for export to New Zealand*.

9.2 During the 5 week period of isolation the donor boars must have been subjected to the isolation, sentinel exposure and health testing requirements of Section 3 of Veterinary Certificate A.

10. SEMEN COLLECTION CENTER

10.1 The semen collection center from which the semen for export originates must be approved for the collection of porcine semen for export to New Zealand according to Appendix 1: *MAF standard for semen collection centers for the collection of porcine semen for export to New Zealand*, including the requirements of section 3.2 relating to approval of PRRS freedom.

10.2 The Supervising Veterinarian of the semen collection center must be a registered veterinary surgeon in the USA and approved by the USDA to supervise the collection of porcine semen for export.

11. IDENTIFICATION

11.1 The identification of the semen donor and the date of collection must be shown on the

veterinary certificates accompanying the semen.

11.2 All straws must be permanently marked with identification of the donor animal and the date of collection. If a code is used for this information, its decipher must accompany the consignment.

12. HEALTH CERTIFICATION

12.1 The animal health certification requirements are stated in Veterinary Certificate A and B which are to be signed by the veterinary surgeon supervising the semen collection center and an official veterinary officer of the veterinary authorities of the country of origin respectively.

12.2 All serological tests must be carried out at a laboratory approved by the government veterinary authorities of the exporting country. Copies of laboratory reports for all testing conducted in accordance with the requirements of Veterinary Certificate A must accompany the consignment to New Zealand.

13. TRANSPORT TO NEW ZEALAND

The semen for export to New Zealand must be transported in transport containers which have been sealed with an official seal of the government veterinary authorities of the exporting country. The number of the seal must be recorded in the Veterinary Certificate B.

14. BIOSECURITY CLEARANCE

On arrival in New Zealand the documentation accompanying the consignment will be checked by an Inspector under the Biosecurity Act 1993 and, providing it complies with the conditions of this import health standard, and the seal of the transport container remains intact, a biosecurity clearance will be issued and it will be released to the importer.

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

ZOO-SANITARY CERTIFICATE:

Species: PIG SEMEN
To: NEW ZEALAND
Import Permit Number

Exporting Country: UNITED STATES OF AMERICA
Department: UNITED STATES DEPARTMENT OF AGRICULTURE
Service: ANIMAL AND PLANT HEALTH INSPECTION SERVICE

I: INFORMATION CONCERNING THE DONOR ANIMAL

Breed:
Identification:
Herd of origin :

II: INFORMATION CONCERNING THE SEMEN

Date of collection:
Number of doses:
Identification of straws:

III: ORIGIN OF THE SEMEN

Name and address of semen collection centre:
.....

IV: DESTINATION OF THE SEMEN

Name and address of importer:
.....

V: SANITARY INFORMATION

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

VETERINARY CERTIFICATE - A.

I, _____, the Government Veterinary Officer or Government approved veterinary surgeon (herein called the Supervising Veterinarian) appointed to the semen collection center certify with respect to the donor boars and semen identified in the attached Zoosanitary Certificate that:

1. DONOR BOARS

The donor boars have been resident in the USA and free from all quarantine restrictions for the twelve months prior to entry into isolation prior to collection of semen for export to New Zealand.

2. HERDS OF ORIGIN

2.1 The herd of origin of the donor boars has had no clinical or serological evidence of the following diseases during the 12 months prior to the entry of the donor boars into isolation prior to collection of semen for export to New Zealand:

Aujeszky's disease
Q fever
vesicular stomatitis

Brucella suis
transmissible gastroenteritis

2.2 After due enquiry and examination of any relevant records, I am satisfied that the donor boars originate from herds which have never recorded a clinical case of Porcine Reproductive and Respiratory Syndrome (PRRS).

2.3 After due enquiry and examination of any relevant records, I am satisfied that the donor boars originate from herds which have never used a modified live PRRS virus vaccine nor introduced pigs from herds that have used a modified live PRRS virus vaccine.

2.4 The donor boars originate from herds from which within two months prior to the date of entry of the donor boars into the isolation facility, a number of grower pigs at least equal to that calculated below (Cannon and Roe, 1982) has been tested using an approved multi-valent ELISA test for PRRS with a negative result in each case:

Number of growers tested	=	$(1 - (1 - \frac{*}{N})^{1/n})(N - n/2) + 1$
Where, N	=	the number of grower pigs in the herd
*	=	the level of confidence (=0.99)
n	=	the minimum expected number of seropositive pigs
	=	$0.10 \times (N)$

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

3. ISOLATION

3.1 Prior to export of semen to New Zealand, the donor boars have completed a 5 week period of isolation in a facility which meets the location and facilities requirements of Sections 1 and 2 of Appendix 1 *MAF standard for semen collection centers for the collection of porcine semen for export to New Zealand.*

3.2 During the 5 week period of isolation:

EITHER 3.2.1 the entry of pigs into the isolation facility has not occurred once an isolation group has been established and begun the 5 week period of isolation (i.e. an "all-in all-out" approach to isolation).

OR 3.2.2 the entry of pigs into the isolation facility has occurred once an isolation group has been established and begun the 5 week period of isolation (i.e. a continuous flow approach to isolation), but all donor boars have completed a full 5 week period of isolation.

3.3 All pigs undergoing the 5 week isolation period were exposed daily throughout the isolation period to direct contact with at least an equal number of sentinel grower pigs, and the total number of pigs in the isolation facility was at least ten (10) at all times.

3.4 The sentinel grower pigs used met the following criteria:

3.4.1 they are aged between 12 and 24 weeks of age;

3.4.2 they are derived from 3 or more herds which meet the requirements of Section 2.4 above.

(N.B. Potential donor boars aged between 12 and 24 weeks of age can act as sentinels for other donor boars, so long as the requirements of 3.3 above are met and pigs acting in a sentinel capacity are derived from three or more herds.)

3.5 During the isolation period, the donor boars and the sentinel grower pigs were tested for porcine reproductive and respiratory syndrome (PRRS) using an approved multi-valent ELISA test, on two occasions at the start and finish of the isolation period, with a negative result in each case.

3.6 During the final seven (7) days of the isolation period, the donor boars were tested in the following manner, with a negative result in each case:

3.6.1 for Aujeszky's disease using:

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

EITHER: 3.6.1.1 in the case of unvaccinated pigs, either the serum neutralization test or ELISA;

OR: 3.6.1.2 in the case of g1 deleted vaccine vaccinated pigs, the ELISA with g1 deleted antigens.

(N.B. Delete whichever of 3.6.1.1 or 3.6.1.2 is not applicable)

3.6.2 for vesicular stomatitis (Indiana or New Jersey strains) using the serum neutralization test.

3.7 During the period of isolation the donor boars have been subjected to the following testing or treatment for leptospirosis:

EITHER: 3.7.1 a microscopic agglutination test for *Leptospiriosis interrogans* serovars pomona, grippityphosa, tarassovi, hardjo, bratislava and ballum, with a negative result;

OR: 3.7.2 two injections of streptomycin 14 days apart, at a dose rate of 25 mg per kg liveweight.

(N.B. Delete whichever of 3.7.1 or 3.7.2 above is not applicable)

4. SEMEN COLLECTION CENTER

4.1 The semen has been collected at a semen collection center which is under the supervision of a veterinary surgeon and which has been approved by the United States Department of Agriculture for the export of porcine semen to New Zealand, according to the criteria detailed within Appendix 1 *MAF standard for semen collection centers for the collection of porcine semen for export to New Zealand*, including the requirements of section 3.2 relating to approval of PRRS freedom.

4.2 The semen collection center and isolation facility has had no clinical or serological evidence for the following diseases during the 12 months prior to the collection of semen for export to New Zealand:

Aujeszky's disease

Brucella suis

Porcine respiratory and reproductive syndrome Q fever

transmissible gastroenteritis

vesicular stomatitis

4.3 The semen collection center and isolation facility has had no clinical evidence of swine influenza, porcine epidemic diarrhea or hemagglutinating encephalomyelitis in the 30 days prior to the date of collection of semen for export to New Zealand.

4.4 During the period of residency in the semen collection center, from the time of completion of

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

the isolation period until completion of semen collection for export to New Zealand, the donor boars have remained isolated from all animals not of the same tested health status. (N.B. All in-contact pigs must have been subjected to the process of isolation and testing as detailed in 3 above).

5. SEMEN COLLECTION

On the dates of collection of the semen, none of the animals in the semen collection center showed any clinical evidence of infectious or contagious disease notifiable by order or regulation in the country of origin, or leptospirosis.

6. SEMEN PROCESSING

6.1 All products of animal origin, other than egg yolk, used in the collection, processing and storage of the semen were screened for adventitious viruses including tests for cytopathology in appropriate cell cultures, for hemagglutinating and hemadsorbing viruses, and for pestiviruses by immunoperoxidase or immunofluorescence techniques with negative results in each case.

6.2 All biological products were handled in a manner which ensures their sterility was maintained.

6.3 Antibiotics have been added to the semen prior to freezing to achieve an effect at least equivalent to the following dilutions:

not less than 500 IU per ml streptomycin,
500 IU per ml penicillin,
150 μ g per ml lincomycin,
300 μ g per ml spectinomycin.

6.4 Immediately after the addition of the antibiotics the diluted semen has been kept at a temperature of at least 15°C for a period of not less than 45 minutes.

7. POST COLLECTION TESTING

Not less than 21 days and not more than 42 days after the last collection of semen for export to New Zealand each donor boar was subjected to the following tests:

7.1 for transmissible gastroenteritis using a serum neutralization test with:

EITHER 7.1.1 negative results;

OR 7.1.2 positive results, in which case the samples were retested using a specific competitive blocking enzyme linked immunosorbent assay (ELISA) to differentiate transmissible gastroenteritis (TGE) from

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

porcine respiratory corona virus (PRCV). The result is negative for
TGE;

(N.B. Delete whichever of 7.1.1 or 7.1.2 as appropriate)

7.2 for Q fever using a complement fixation test (CFT) with negative results;

7.3 for PRRS using an approved multi-valent ELISA test with negative results;

8. SEMEN STORAGE

8.1 After processing, the semen was stored in previously sterilized flasks containing fresh nitrogen not previously used for any other purpose.

8.2 Prior to shipment to New Zealand, the semen has been stored under quarantine conditions at the semen collection center for a minimum of 25 days or until the results of the post collection testing are known, whichever is the greater, and until at least 5 weeks after completion of isolation in the case of semen collected from donor boars whose isolation prior to entry into the semen collection center has been conducted according to 3.2.2 above (i.e. a continuous flow approach to isolation).

8.3 During the period from collection of the semen to dispatch to New Zealand there has been no clinical or serological evidence of infectious or contagious disease, including PRRS, in pigs in the semen collection center.

8.4 Any container servicing has been completed under the supervision of the veterinarian appointed to the semen collection center and has been conducted in a manner that prevents contamination of the container or its contents.

9. LABORATORY TESTING

All serological tests have been carried out at a laboratory approved by APHIS. Copies of laboratory reports for all serological testing conducted in accordance with the requirements of Veterinary Certificate A are accompanying the consignment to New Zealand.

.....
Supervising Veterinarian

.....
Date

appointed to the Semen Collection Center.

Name and address of office:

.....

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

VETERINARY CERTIFICATE - B.

I, _____, a Veterinary Officer of the United States Department of Agriculture certify with respect to the semen for export and donor boars identified in the attached Zoosanitary Certificate that:

1 COUNTRY FREEDOM DECLARATION

During the 12 month period preceding the first date of collection of semen for export to New Zealand, and during the minimum 30 days period of storage of the semen after final collection for export to New Zealand, the United States of America has been free from:

rinderpest	swine vesicular disease
classical swine fever	African swine fever
foot and mouth disease	Japanese B encephalitis
enterovirus encephalomyelitis	

2 ENDORSEMENT

- 2.1 The semen collection center from which the semen for export originates is approved for the collection of porcine semen for export to New Zealand according to Appendix 1: *MAF standard for semen collection centers for the collection of porcine semen for export to New Zealand*, including the requirements of section 3.2 relating to approval of PRRS freedom.
- 2.2 The Supervising Veterinarian of the semen collection center is a registered (licensed) veterinary surgeon in the USA and approved (accredited) by the USDA to supervise the collection of porcine semen for export.

3. SEMEN FOR EXPORT

- 3.1 The semen for export has been stored at a place approved by the United States Department of Agriculture during the period between semen collection and shipment to New Zealand.
- 3.2 Prior to export, the transport container containing the semen for export to New Zealand has been sealed with an official seal of the United States Government containing the unique identification number or mark:

.....
Veterinary Officer, APHIS
United States Department of Agriculture

.....
Official stamp and Date

Health Certificate No. _____

Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

Name and address of office:

.....

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

APPENDIX 1

MAF STANDARD FOR SEMEN COLLECTION CENTERS FOR THE COLLECTION OF PORCINE SEMEN FOR EXPORT TO NEW ZEALAND

1. LOCATION

- 1.1 The center must be located in a country, or part of the territory of a country, that has been free from the following diseases for a minimum 12 months period prior to entry of the donor boar:

African swine fever	classical swine fever
porcine enterovirus encephalomyelitis	foot and mouth disease
Japanese B encephalitis	rinderpest
swine vesicular disease	vesicular stomatitis

- 1.2 The center must be conveniently located for supervision by either a Government Veterinary Officer or a registered veterinary surgeon with Government approval to supervise the collection of porcine semen for export (herein called the Supervising Veterinarian).
- 1.3 The center must be situated at least 3 kms from any other pig-producing enterprises. In the case of a semen collection center in proximity of less than 3 km to a pig producing enterprise, MAF may consider a request for approval of the semen collection center based upon demonstration of PRRS freedom in the pig producing enterprise to a technical equivalence with this standard.

2. FACILITIES

- 2.1 The facility must be accessible by authorized personnel only. Such personnel (with the exception of veterinary officers who maintain necessary protection and disinfection procedures applicable to an isolation facility) are not to be concurrently employed in nor attending another pig-producing enterprise.
- 2.2 The facility must be roofed and ventilated to prevent resident pigs from coming into contact with any birds.
- 2.3 The facility must be of a permanent-type construction, and internal surfaces in areas in direct contact with pigs must be of materials that they can be readily cleaned and disinfected.
- 2.4 The facility must have facilities for veterinary examination of animals, the collection of samples, and for the segregation and isolation of sick animals under investigation to rule out a diagnosis of infectious or contagious disease.
- 2.5 Semen must be processed in a room or building designated as a laboratory and set aside for

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

that purpose, separate from areas where animals are housed and where semen is collected.
This facility must be cleaned and disinfected before use.

3. APPROVAL

3.1 The center must be approved by the Supervising Veterinarian prior to the commencement of each period of collection of semen for export to New Zealand according to the requirements of sections 1, 2, and 4 of this standard.

3.2 In the case of semen collection centers located in countries which are unable to demonstrate country freedom from porcine reproductive and respiratory syndrome (PRRS) to the satisfaction of NZ MAF, approval of the semen collection center shall require that the center has been determined to be free from PRRS according to the following requirements:

3.2.1 The semen collection center must have a documented absence from PRRS. All pigs entering the semen collection center must originate from herds which, to the best of the Supervising Veterinarian's knowledge, have never recorded a clinical case of PRRS.

3.2.2 The semen collection center must have never used a modified live PRRS virus vaccine nor, to the best of the Supervising Veterinarian's knowledge, introduced pigs from herds that have used a modified live PRRS virus vaccine.

3.2.3 All pigs in the semen collection center must have completed a 5 week period of isolation in a facility which meets the physical requirements of this standard detailed in sections 1 and 2 above (isolation may occur in the semen collection center itself during the approval period of the semen collection center).

3.2.4 While undergoing the 5 week isolation period the pigs must be exposed throughout the isolation period to direct contact with at least an equal number of sentinel grower pigs. The total number of pigs in the semen collection center undergoing isolation must be at least ten (10) at all times.

3.2.5 The sentinel grower pigs used must meet the following criteria:

3.2.5.1 they are aged between 12 and 24 weeks of age;

3.2.5.2 they are derived from 3 or more herds from which within two months prior to the commencement of the isolation period, a number of grower pigs at least equal to that calculated below (Cannon and Roe, 1982) has been tested using an approved multi-valent ELISA test for PRRS with a negative result in each case:

$$\text{Number of growers tested} = (1 - (1 - \frac{1}{N})^{1/n})(N - n/2) + 1$$

Health Certificate No. _____
Valid only if the USDA Veterinary Seal
Appears over the Certificate No.)

Where,	N	=	the number of grower pigs in the herd
	*	=	the level of confidence (=0.99)
	n	=	the minimum expected number of seropositive pigs
		=	0.10 x (N)

- 3.2.6 Potential donor boars which meet the requirements of 3.2.5 above can act as sentinels for other donor boars, so long as the requirements of 3.2.4 above are met and pigs acting in a sentinel capacity are derived from three or more herds.
- 3.2.7 During the isolation period, all pigs undergoing isolation must be tested for PRRS using an approved multi-valent ELISA test, on two occasions at the start and finish of the isolation period, with a negative result in each case.
- 3.2.8 Semen collected from donor boars during the 5 week period of isolation (either during approval of the semen collection center or prior to entry of a donor boar onto an approved semen collection center) will become eligible for export to New Zealand upon successful completion of isolation (i.e., no positive test for PRRS in any donor boar or sentinel simultaneously undergoing isolation).

4. OPERATION

- 4.1 Disease testing, semen collection and semen processing and storage must be supervised by the Supervising Veterinarian.
- 4.2 During the collection period the center must only be occupied by the donor boars and other stock of the same health status.
- 4.3 Personnel attending the pigs must change outer clothing and footwear, and wash thoroughly, before entering the facility and handling the animals. Personnel processing semen must be trained in, and practice, proper disinfection procedures and hygiene techniques.
- 4.4 All equipment used in the feeding, handling and treatment of the pigs at the center must be new or cleaned and disinfected before use and must be dedicated to use on the animals on the center for the duration of the collection period.
- 4.5 All equipment used to collect, process and store the semen and/or which comes into contact with the donor boars of the semen must be new and disposable or cleaned and disinfected before and between uses. Semen must be stored in a secure area.
- 4.6 Any health problems affecting pigs on the center during the collection period must be promptly reported to the Supervising Veterinarian.

Health Certificate No. _____

Valid only if the USDA Veterinary Seal

Appears over the Certificate No.)

- 4.7 A record must be kept by the operator and/or the export agent detailing identification of all pigs on the center and their origins, dates of entry, dates and results of disease tests or investigations, treatment either therapeutic or prophylactic, any departures from good health and condition, inspection visits by the Supervising Veterinarian and any other information relevant to each animal's health status while it is resident on the center.
- 4.8 There must be no unauthorized access to the center and all visitors entries must be logged.